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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/817,595	04/22/1997	ANGELA TURIANO	MARGI-15	8416

7590 06/16/2004

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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 08/817,595	Applicant(s) TURIANO, ANGELA	
	Examiner Christopher H Yaen	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/4/2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-34 and 36-44 is/are pending in the application.
- 4a) Of the above claim(s) 42 and 43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-34 and 36-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Re: Turiano *et al*
Priority Date: 05 August 1994

1. The amendment filed 3/4/2004 is acknowledged and entered into the record. Accordingly, claims 1-24, and 35 are canceled without prejudice or disclaimer, claims 40-44 are newly added.
2. Claims 25-34 and 36-44 are pending. Claims 42 and 43 are withdrawn from further consideration as being dependent and drawn to a non-elected invention. It is noted that claims 42 and 43 are dependent on claim 23 which is canceled nor examined.
3. Claims 25-34, 36-41, and 44 are examined on the merits.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections Maintained - 35 USC § 103

5. The rejection of claims 25-34 and 36-39 and now claims 40-41 and 44 under 35 USC 103(a) as being obvious over Bartorelli *et al* (WO 92/10197) is maintained for the reasons of record. The claims are drawn to a kit comprising allogeneic or xenogeneic MHC molecules extracted from tissue, serum or cells, wherein the MHC molecules are from different species and are separated into different containers. The claims are also drawn to a method of making the kit and a method of treating carcinoma using the said kit. Applicant argues that Bartorelli *et al* is "devoid of any suggestion of the administration of the two different kinds of extract/MHC molecules compositions" (page

6), and further argues that the examiner “demonstrate that a skilled worker first would be motivated to arrive at the idea of using two different kinds of extracts/MHC molecules”. Applicant’s arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record. The cited reference of Bartorelli *et al* teaches a composition that appears to be the same as that instantly claimed, because the source of the extracts and method of preparing the extract composition are similar. According to MPEP 2144.06, “It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art.” In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). In the instant case, the prior art of Bartorelli *et al* specifically suggests that the extract can be derived from more than one source (i.e. sheep or goat tissues), and therefore it would have been obvious to one of ordinary skill in the art to make extract derived from different species. In addition, Bartorelli *et al* teach that the extracts can be dispensed and stored in vials (i.e. containers, see page 4). Because Bartorelli *et al* teaches the storage of the extracts in separate vials, one of skill in the art would find it obvious to combine the vials containing extracts from different species into a kit. Moreover, Bartorelli *et al* taught that the administration of the extracts could be effective in the treatment of neoplastic disease, and specifically teaches that the extract were effective in the treatment of epithelial based cancers (see tables 2,4, and 5) and therefore one of

skill in the art would readily predict that these results would be indicative of the treatment of carcinomas in general.

Therefore, based on the availability of extracts derived from different species and the ability to store such extract in separate containers, one of ordinary skill would be motivated to combine the vials comprising extract derived from different species into a single kit, because the extracts were taught to elicit the same effect on the treatment of neoplastic diseases as demonstrated by Bartorelli *et al*. Furthermore, the combination of two elements that are known to have the same function is considered obvious (see In re Kerkhoven). Furthermore, one of ordinary skill in the art would have found reasonable motivation to treat carcinomas with the extracts derived from different species because there appears to be no significant difference in the type of response generated against epithelial based cancers, because Bartorelli *et al* teaches that the extract derived from goat are more convenient are chosen based on practicality (see page 3 in particular). One of ordinary skill in the art would have expect a reasonable amount of success in doing so because Bartorelli *et al* teaches the effectiveness of the tissue extracts and does not state that extract derived from different species would cause any noticeable difference in the treatment of disease and only specifically chooses one species over another based on the availability and convenience (see page 3 in particular). Therefore, the rejection under 35 USC 103(a) is maintained for the reasons of record.

With regard to the newly rejected claims, Bartorelli *et al* specifically claim that the extract can be in the range of 10-50 kDa (see claim 2, page 33) and because a calf is

closely related to both sheep and goat, one of skill in the art would reasonable expect that the extracts derived from a calf would be substantially similar to those of either sheep or goat. Furthermore, Bartorellie *et al* teach that the daily administration of the extracts (see page 19). It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use extracts of 43, 13, 33, 34, or 29 kDa, wherein the extract are derived from calf because Bertorelli *et al* already taught that the extract can be in the range of 10-50 kDa, and that there was little difference between sheep and goat extract and used sheep primarily because of convenience. This difference also underscore the alternating daily administration of extracts, wherein one of skill in the art would expect the results obtained from alternating to be the same, because the specification has not provided and evidence of unexpected result.

Conclusion

6. No claim is allowed.
7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

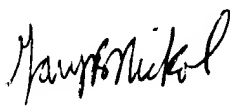
shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen
Art Unit 1642
June 10, 2004


GARY NICKOL
PRIMARY EXAMINER